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John Muraca

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SUITE 700

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EXAMINER

NGUYEN, TRAN N

ART UNIT

PAPER NUMBER

3626

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04/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/853,703	Applicant(s) MURACA, JOHN	
	Examiner Tran Nguyen	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-21,23-35 and 37-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-21,23-35 and 37-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/21/2008, 03/24/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

This communication is in response to the communication filed 03/24/2008.

Pending claim(s): 1-7, 9-21, 23-35, 37-44. Cancelled claim(s): 8, 22, 36. Amended claim(s): 1, 14-15, 28-29, 41-43.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 03/21/2008, 03/24/2008 is entered and considered by Examiner.

Response to Amendment

As per the objection of claims 14, 28, 41-42 for formalities imposed in the previous Office Action, this objection is hereby withdrawn in view of Applicant's amendment to claims 14, 28, 41-42.

As per the rejection of claims 1-7, 9-21, 23-35, 37-44 under 35 USC 112, second paragraph imposed in the previous Office Action, this rejection is hereby withdrawn in view of Applicant's amendment to claims 1, 15, 29, 43.

Claim Objections

Applicant is advised that should claim 1 be found allowable, claim 44 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two

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claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 1-7, 9-11, 15-21, 23-25, 29-35, 37-39, 43-44 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5924074) in view of Johnson (5664109), Hacker (6988075), and Applicant Admitted Prior Art (AAPA).

As per claim 1, Evans teaches a system (reads on "an apparatus") (Abstract), comprising:

(a) an EMR system (reads on “a computer system”) (Abstract, column 2 line 21) capable of communicating with portable computers (It is noted that communicating with portable computers are considered to be “executing portability enabling software”) (Abstract);

(b) wherein the EMR system is capable of sharing patient medical records between a plurality of external systems (Figure 1 label 106, “EXTERNAL DATA”, Figure 12, Figure 13 label 219, Figure 17A-B) via a data handler and a communication interface (Figure 16 label 272, 274, column 10 line 18-35), and a plurality of legacy systems via a data converter (column 12 line 35-53, Figure 23);

(c) wherein the EMR system is capable of supporting communication among a variety of hardware components (reads on “disparate... computer platforms”) using a variety of operating systems (column 13 line 31-56).

Notwithstanding the above, Johnson teaches a central medical record repository (Abstract) capable of providing standardized patient records to a plurality of provider systems, wherein each provider system need not adopt a global patient identifier or record standard (reads on “disparate operating systems”) (column 2 line 66-10).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Johnson within the embodiment of Evans with the motivation of eliminating multiple patient identifiers for the same patient, allowing the provider to retain its own internal identifier and format, and providing backward compatibility (Johnson; column 2 line 6-10).

Evans further teaches:

- (a) the hardware components comprising:
 - (i) a PC (Figure 24 label 412, 416, 418);
 - (ii) a pen-based portable computer (reads on “a hand-held device”) (Figure 24 label 420);
 - (iii) a network (Figure 24 label 404, 414);
- (b) wherein the EMR system is capable of populating and updating the patient record with text (Figure 14 label 223) and image data (Figure 14 label 225) from legacy data systems (column 8 line 57-60) and external sources (column 8 line 18 to column 9 line 37) (reads on “access and mapping information between a database of text and image data and the medical records system”);
- (c) wherein image data is stored in a plurality of formats (reads on “a plurality of image and text formats”) (Figure 14 label 225).

Evans teaches that the EMR system is capable of supporting communication among a variety of hardware components (reads on “interfacing with the plurality of image and text formats and the disparate operating systems”) using a variety of operating systems (column 13 line 31-56).

Notwithstanding the above, Johnson teaches that the central repository is capable of providing patient records in any text and image format (column 6 line 44-62) to a plurality of client systems, including providing paper copies if the client system is unable to display data (reads on “disparate operating systems”) (column 15 line 6-18).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Johnson within the embodiment of

Evans and Johnson with the motivation of providing backward compatibility (Johnson; column 2 line 6-10).

Evans further teaches:

(a) wherein the EMR system is capable of capturing patient data during a patient encounter with a physician (reads on “patient episode data”) (column 6 line 10 line 10-36, Figure 4) and controlling access thereto via a password system (reads on “a secure file”) (column 15 line 21-32);

(b) wherein the patient data comprises e-mails from other healthcare providers (column 8 line 67 to column 9 line 1).

Evans further teaches that the patient data repository comprises a relational database supporting the Open Database Connectivity (ODBC) model, wherein ODBC is an application program interface (API) capable of enabling client applications running under Microsoft Windows to access data from a variety of data sources, including relational and non-relational DBMS, wherein these data sources may reside on a client machine or on a remote server (column 14 line 8-25).

Evans further teaches a patient locator capable of locating patient data in a plurality of external sources (column 8 line 18 to column 9 line 37).

Examiner submits that the ODBC model and patient locator of Evans are considered to be a form of “a master control file” when viewed in light of Applicant’s specification.

Notwithstanding the above, page 3 paragraph 3 of Applicant’s specification reads as follows:

“One way of providing a common set of medical information communications protocols, or common standards, is by an architecture which includes the use of a master control file. A master control file (or MCF) is middleware software storing information which, when read by a computer program referred to as an engine, provides an interface between an application program and the WINDOWS operating system. The master control file (or MCF) provides an open, **interoperable, platform and language independent distributed (MCF) architecture**. This approach has been enormously successful and has been **adopted by numerous large firms** around the world as the basic architecture for their complex Patient Record information systems. This infrastructure provides a great deal of power, scalability, and interoperability.” (emphasis added)

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of AAPA within the invention as disclosed by Evans and Johnson with the motivation of enabling client applications to access data from a plurality of external data sources (Evans; column 14 line 11-14).

Evans, Johnson, and AAPA do not teach:

- (a) “transmitting the secure file as an e-mail attachment”;
- (b) “retrieving the patient episode data from the secure file”;
- (c) “storing the patient episode data in the medical records system”.

Hacker teaches a system (Abstract) capable of:

- (a) attaching updated information from the patient visit to an e-mail (column 8 line 41-42);

(b) translating the attached information by software on the server (It is noted that translating data is considered to be “retrieving”) (column 8 line 43);

(c) updating the patient medical record on the medical information database with the translated data (column 8 line 44-45).

Evans teaches a password system, as discussed above and incorporated herein.

It is also noted that the official notice taken in the previous Office Action is taken to be AAPA because Applicant failed to traverse Examiner's assertion. Page 7 of the previous Office Action reads as follows: “It is well known that emailing data over a network requires some form of security for the data”.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Hacker and AAPA within the invention as disclosed by Evans, Johnson, and AAPA with the motivation of providing privacy for patient records (Hacker; column 6 line 1-10), and of providing convenience to medical providers who have their own electronic medical record system and only need access to very little “outside” medical information (Hacker; column 8 line 25-34).

As per claim 2, Evans teaches a graphical user interface (reads on “medical software”) capable of being deployed on a wireless pen-based or laptop computer (Figure 24, column 6 line 9-55, column 13 line 12-30).

As per claim 3, Evans teaches that the ODBC/API is capable of enabling client applications to access data from a variety of data sources, wherein the client is capable

of storing, annotating, entering, and accessing patient medical records stored in the patient data repository (column 5 line 1-28, column 14 line 8-25).

As per claim 4, Evan teaches a data manager/patient locator capable of creating a data structure comprising a patient identifier, wherein the data structure comprises pointers to data structures having data within a patient record captured by a pointer of care system (e.g., X-ray images), wherein there exists a plurality of data structures created by the patient locator comprising patient data, interface files, clinical data, progress notes (Figure 13), wherein the files comprises patient data types (reads on “field names, attributes”) (Figure 12 column 8 line 29-60).

As per claim 5, Evans teaches database tables comprising a plurality of field names, comprising a patient identifier (Figure 13), wherein the EMR system is capable of using the field names to locate, store, and retrieve data (Figure 13, column 5 line 1-28, column 8 line 29 to column 9 line 37).

As per claim 6, Evans teaches a plurality of pointers to a plurality of patient data structures, comprising a reference database, wherein the patient data structure and patient locator are capable of using the pointers to locate, store, and retrieve data (Figure 13, column 5 line 1-28, column 8 line 29 to column 9 line 37).

As per claim 7, Evans teaches a plurality of pointers to image data, wherein the EMR system is capable of displaying the image data when the healthcare provider accesses the files using the data manager (Figure 13-14, column 4 line 64 to column 5 line 27, column 8 line 29 to column 9 line 37).

As per claim 9, Evans teaches an electronic medical records system capable of being accessed over the Internet (Figure 24, column 2 line 20-45, column 16 line 2-20).

As per claim 10, Evans teaches that the EMR system is capable of enabling healthcare providers to remotely enter, access, process, analyze, and annotate data from patient records in real-time (column 5 line 1-28).

As per claim 11, Evans teaches that the healthcare providers are capable of accessing patient data remotely (reads on "health indicators") (Figure 24, column 5 line 1-28, column 7 line 5-40, column 13 line 1-30).

As per the set of claim(s): 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 29, 30, 31, 32, 33, 34, 35, 37, 38, 39, 43, 44, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 1, 1, respectively, and incorporated herein. See MPEP 2106.01(I).

Claim(s) 12, 26, 40 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans in view of Johnson, Hacker, and AAPA as applied to parent claim, 9, 15, 29 above, respectively, and further in view of Swanson (6112183).

As per claim 12, Evans teaches that the EMR system is capable of capturing data in a point of care system (column 16 line 2-20) and securing data using a tiered-password system (column 15 line 8-32).

Evans, Johnson, and Hacker do not teach “compresses, encrypts, and encapsulates patient episode data into the secure file”.

It is noted that the official notice taken in the previous Office Action is taken to be AAPA because Applicant failed to traverse Examiner's assertion. Page 10 of the previous Office Action mailed 05/16/2006 reads as follows: “it is well known in the art to compress data, encrypt data, and encapsulate patient data”.

Swanson also teaches encryption, compression, and encapsulation (column 2 line 26-31).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Swanson and AAPA within the invention as disclosed by Evans, Johnson, Hacker, and AAPA with the motivation of providing superior protection of patient data (Evans; column 15 line 29-32).

As per the set of claim(s): 26, 40, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 12, 26, respectively, and incorporated herein. See MPEP 2106.01(I).

Claim(s) 13-14, 27-28, 41-42 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans in view of Johnson, Hacker, AAPA, and Swanson as applied to parent claims 12, 26 above, and further in view of Haudenschild (6665647).

As per claims 13-14, Evans, Johnson, Hacker, AAPA, and Swanson do not teach:

(a) “transmits the secure file to a repository mail sever, which de-encapsulates and uncompresses the secure file and stores the de-encapsulated, uncompressed secure file into a patient medical record”;

(b) “a messages is transmitted to an assigned physician notifying the assigned physician of the receipt of the patient episode data”.

Haudenschild teaches a system (Abstract) capable of encrypting sensitive data at one end of transmission and decrypting the encrypted data at the other end of transmission, and notifying all parties via messages (column 6 line 48-65).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Haudenschild within the invention as disclosed by Evans, Johnson, Hacker, AAPA, and Swanson with the motivation of protecting sensitive data (Haudenschild; column 6 line 48-65).

As per the set of claim(s): 27, 28, 41, 42, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 13, 14, 27, 28, respectively, and incorporated herein. See MPEP 2106.01(I).

Response to Arguments

Applicant's arguments filed 03/10/2008 have been fully considered but they are not persuasive.

On page 9-10 Applicant requests withdrawal or evidentiary support of the Official Notice previously given.

First, Applicant's traversal is not timely because the Official Notice was previously given in the Office Action mailed 05/16/2006, and Examiner clearly indicated in the Office Action mailed 09/10/2007 that Applicant did not traverse Examiner's assertion of Official Notice. See MPEP 2144.03(C). Examiner notes the lack of the term "Official Notice" in the Office Action mailed 09/10/2007; however, Applicant is invited to provide citation of required terminology when taking Official Notice.

Second, even assuming *arguendo* that Applicant's traversal is timely, Applicant's traversal is inadequate because Applicant did not specifically point out then supposed errors in Examiner's action, including why the noticed fact is not considered to be old and well established in the art. See MPEP 2144.03(C).

Third, assuming *arguendo* that Applicant's traversal is adequate:

As per claim 1, Examiner submits class 726, subclass 14 directed towards security protocol governing the format of message exchange between two communications terminals to prevent unauthorized intrusion or interference. Examiner further submits that since Evans teaches accessing patient records with a password system (column 15 line 21-32) and Hacker teaches attaching updated information from the patient visit to an e-mail (column 8 line 41-42), the combined teachings of the prior art also suggest Applicant's claimed invention because the feature of e-mail security is known in the prior art.

As per claim 12, Examiner submits Keene (5325294), who teaches using a generated patient identifier so that no information about the patient may be gleaned from the identifier (Abstract). The teachings of Keene are an improvement over using insecure identifiers, such as name, etc.

On page 10 Applicant asserts that Examiner has applied impermissible hindsight; however, Applicant does not argue which portion of the rejection Applicant considers to be impermissible hindsight.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

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reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

As per claims 1, 15, 29, 43, on page 10 Applicant argues that the applied art do not teach “a master control file as recited”.

Evans teaches an EMR system capable of sharing patient medical records between a plurality of external systems (Figure 1 label 106, “EXTERNAL DATA”, Figure 12, Figure 13 label 219, Figure 17A-B) via a data handler and a communication interface (Figure 16 label 272, 274, column 10 line 18-35), and a plurality of legacy systems via a data converter (column 12 line 35-53, Figure 23), wherein the EMR system is capable of supporting communication among a variety of hardware components (reads on “disparate... computer platforms”) using a variety of operating systems (column 13 line 31-56).

Examiner considers the system of Evans to employ a form of “master control file”.

Notwithstanding the above, Johnson teaches a central medical record repository (Abstract) capable of providing standardized patient records to a plurality of provider systems, wherein each provider system need not adopt a global patient identifier or record standard (reads on “disparate operating systems”) (column 2 line 66-10).

Examiner considers the system of Johnson to employ a form of “master control file”.

Notwithstanding the above, page 3 paragraph 3 of Applicant's specification reads as follows:

"One way of providing a common set of medical information communications protocols, or common standards, is by an architecture which includes the use of a master control file. A master control file (or MCF) is middleware software storing information which, when read by a computer program referred to as an engine, provides an interface between an application program and the WINDOWS operating system. The master control file (or MCF) provides an open, **interoperable, platform and language independent distributed (MCF) architecture**. This approach has been enormously successful and has been **adopted by numerous large firms** around the world as the basic architecture for their complex Patient Record information systems. This infrastructure provides a great deal of power, scalability, and interoperability." (emphasis added)

Examiner considers AAPA to teach a form of "master control file".

Applicant's arguments with respect to claim 1 on page 11 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Behram (5499293) teaches providing patient data security by compression.

Conner (5579393) teaches providing a secure patient data interchange.

The new ground(s) of rejection presented in this Office action, if any, was/were necessitated by Applicant's amendment. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tran (Ken) N. Nguyen whose telephone number is 571-270-1310. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. N./

Examiner, Art Unit 3626

04/18/2008

/C Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626